PUBLICCITIZEN

1600 20th Street, NW • Washington, D.C. 20009 • 202/588-1000 • www.citizen.org

180-Day Generic Exclusivity Expansion Unlikely to Bring Down Drug Prices; May Delay Price-Lowering Competition

Among proposals to lower prescription drug prices under consideration in legislation and reportedly by the Trump Administration's "Drug Pricing and Innovation Working Group" is to grant a new 180-day exclusivity period to generic firms that are the first to seek approval for a competitor to a sole-source product without exclusivity. The stated goal of this proposal is to bring generic competition to markets that would otherwise face no competition, and thus foreclose the potential for opportunistic companies to engage in price gouging. Unfortunately, such exclusivity may have the unintended consequence of delaying more robust generic competition.

The FDA Reauthorization Act of 2017 (H.R. 2430) includes an amendment[i], introduced by Reps. Schrader (D-Ore.) and Bilirakis (R-Fla.), that contains some positive and innocuous provisions; however, it also includes a provision providing 180-day exclusivity for first generics when an application is submitted for an off-patent, no-exclusivity drug.[1] During that time, no other firm would be permitted to market a competing generic drug.

Exclusivity is Not the Answer to the Small Market Problem

Ostensibly, proponents of this measure are seeking to provide incentive to bring a first generic to market where there would otherwise be no competition. The apparent goal is to help prevent monopolists like Martin Shkreli from sharply increasing the price of a medicine where there are no patent or marketing exclusivities blocking competition. However, the proposed 180-day exclusivity expansion misdiagnoses the underlying cause for the lack of competition for off-patent, sole-source drugs. In turn, it would be unlikely to increase competition for those drugs.

In its investigation on sudden price spikes in off-patent prescription drugs, the Special Committee on Aging of the United States Senate found that a key factor in the business model of bad actors like Retrophin, Turing, Valeant and Rodelis was the small market for the drug that underwent a severe price spike.[ii] The Committee's report states as one of the key factors in these pricing abuses that, "[t]he company selected a drug that served a *small market*, which were not attractive to competitors and which had dependent patient populations that were too small to organize effective opposition, giving the companies more latitude on pricing."

The evidence does not suggest that generic firms are concerned with potential competition from other generics, so the grant of exclusivity would be unlikely to induce more competition in this scenario. Rather, the Special

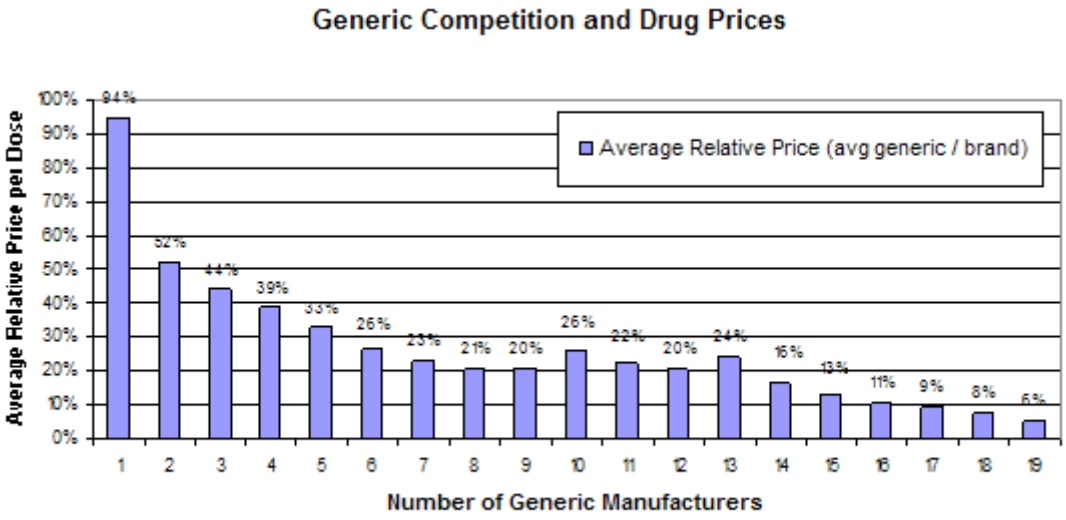
[1] The amendment provides 180 days of marketing exclusivity to manufacturers of so-called "competitive generic therapies", defined as a firm that first applies for marketing approval for a drug without exclusivity that has not more than one approved drug product. The version of the amendment which passed out of the House Energy and Commerce Health Subcommittee as well as that which passed out of the House Energy and Commerce committee included a broader grant of exclusivity to all first generics for drugs that had no blocking patents or exclusivities at the time of ANDA approval, rather than only those with no blocking patents or exclusivities at the time of submission. This narrower standard is a welcome improvement, but may still limit competition.

Committee on Aging report shows that the small size of the potential market and thus the limitation on the potential profit is the reason for the lack of generic competition for off-patent, sole-source drugs that have had their prices spiked by prescription drug corporations. A special grant of 180-day exclusivity to a first generic would not address this underlying problem, and therefore it would be unlikely to increase competition or lower drug prices.

Further, Food and Drug Administration (FDA) Commissioner Scott Gottlieb, in his former role as resident fellow at the American Enterprise Institute, a conservative think tank, argued that regulatory costs are too high to induce generic competition in a small market.[iii] Insofar as that dissuades potential competitors from entering the market, rather than providing a grant of exclusivity, it would make more sense to provide a direct subsidy for regulatory approval costs.

A New 180-Day Exclusivity Period Would Have Negative Consequences, Raising Drug Prices

Beyond not achieving its stated goal, the 180-day exclusivity provision may have negative consequences that, perversely, result in increased medicine prices. The FDA has shown that a first generic competitor provides a small effect on reducing drug prices. It is the second and subsequent generic competitors that provide the more robust competition that is necessary to have a more substantial impact on drug prices.



Source: FDA analysis of retail sales data from IMS Health, IMS National Sales Perspective (TM), 1999-2004, extracted February 2005 [iv]

Providing a new 180-day exclusivity period when a company submits an application for a first generic of an off-patent, no-exclusivity drug, rather than granting 180-day exclusivity only for those generics that contain a paragraph IV patent certification, would foreclose the possibility for more robust competition to drive down prices within that six-month timeframe.[v]

Conclusion

As Congress moves forward with finalizing and voting on the FDA Reauthorization Act of 2017, the final bill should not include any provision like that which passed the House providing for a new 180-day exclusivity period for firms that are first to submit a generic application for off-patent, no-exclusivity products.

---

[i] http://docs.house.gov/meetings/IF/IF00/20170607/106096/BILLS-115-2430-W000791-Amdt-3.pdf
[ii] https://www.aging.senate.gov/imo/media/doc/Drug%20Pricing%20Report.pdf
[iii] http://www.aei.org/publication/how-obamas-fda-keeps-generic-drugs-off-the-market/

[iv] Table available at
https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm129385.htm

[v] Evidence from FDA's data on first generic drug approvals in 2016 and paragraph IV patent certifications supports this concern. The FDA lists 73 products on its "First-Time Generic Drug Approvals 2016" list.[1] Of those 73 products, 19 are not listed on the FDA's published list of drugs that have received "Paragraph IV Patent Certifications"[2].

Had the 180-day exclusivity provision that advanced out of the House Energy and Commerce committee been law in 2016, unlike under current law, these 19 products may have been subject to the special exclusivity period, though it is unclear which products received ANDA submission under paragraph iii. Paragraph iii products would not have been eligible for the proposed 180-day exclusivity. While deeper inspection of FDA information on those 19 products raises some questions -- two of the 19 products had 0 therapeutic equivalent products listed, including lacking the listing of the originator drug that was listed as the referenced list drug in the FDA "First-Time Generic Drug Approval" list, and the originator drug not listing the "first generic" product as a therapeutic equivalent on its page; another had an originator upon which more than thirty products were listed as therapeutic equivalents, but the product listed on the FDA "First-Time Generic Drug Approval" list listed no therapeutic equivalents listed on its ANDA page -- of those 19 products, at least six products had subsequent therapeutically equivalent generics approved within six months. For three out of those six products, subsequent generic marketing approvals were granted for therapeutically equivalent products within eight days or less (one of those six products had a therapeutically equivalent generic receive approval on the same day, in addition to a subsequent generic approval within eight days). For more information see
https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/ANDAGenericDrugApprovals/ucm539767.htm;
https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM293268.pdf